

**GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA**

UNSTARRED QUESTION NO:2457
ANSWERED ON:04.12.2002
NATIONAL DRUG AUTHORITY
P.R. KHUTE

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

- (a) whether the Government propose to establish the National Drug Authority; and
- (b) if so, the details thereof?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI A. RAJA)

(a) & (b) Drug Policy 1994 had recommended the setting up of a National Drug Authority to undertake the regulatory functions performed by the Central Drug Standard Control Organisation in addition to assuming many new responsibilities. This would inter alia require major structural changes in the existing regulatory system, where licensing of manufacturers etc., as well as enforcement of the Drugs and Cosmetics Act, 1940 and Rules made thereunder, are primarily done by the State authorities. Strengthening of the existing capacity of the Central Drugs Standard Control Organisation (CDSCO) would be necessary before undertaking the new responsibilities. There is currently no such proposal.